IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Thomas Dag Horn et al.	Group Art Unit: 1642
Serial No.:	10/081,185	Examiner: Gary B. Nickol
Filed:	February 25, 2002	Docket No.: 110.004US2
Title:	IMMUNOTHERAPY OF EPITHELIAL TUMORS USING INTRALESIONAL INJECTION OF ANTIGENS THAT INDUCE A DELAYED TYPE HYPERSENSITIVITY REACTION	

DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Thomas Dag Horn, declare and say as follows:

1. I am an inventor of the subject matter claimed in the above-identified U.S. Patent Application Serial No. 10/081,185, filed February 25, 2002, and of its parent U.S. Patent Application Serial No. 09/344,357, filed June 25, 1999, now U.S. Patent No. 6,350,451, of which U.S. Patent Application Serial No. 10/081,185 is a divisional patent application.

2. I have reviewed the Office Action mailed July 26, 2004 in relation to the above-identified patent application and have reviewed Bostwick (U.S. Published Patent Application No 2002/0009429 A1) cited by the Examiner in the Office Action. I make this declaration in support of the patentability of the claims of U.S. Patent Application Serial No. 10/081,185.

3. I conceived the claimed invention of U.S. Patent Application Serial No. 10/081,185 before the filing date of Bostwick of January 29, 1999, and diligently pursued development of the invention from my conception of the invention before January 29, 1999 until the filing of U.S. Patent Application Serial No. 09/344,357 on June 25, 1999.

4. My conception of the claimed invention and diligence in pursuing it is evidenced by the attached letter from Fred H. Faas, M.D., which is dated before January

29, 1999 (date redacted). The letter is an approval letter to proceed with use of mumps and candida intradermal skin test antigens to treat human patients afflicted with Verruca vulgaris (common warts). The letter refers to the use of mumps and candida antigens. At the time of the letter, I also believed that any antigen that induced a cutaneous delayed-type hypersensitivity response, including bacterial antigens, would successfully treat warts and other benign epithelial tumors. At the time of this letter from Dr. Faas and at the time of submitting the protocol that the letter refers to, I planned to combine two or more antigens in a single composition to be administered for treatment of warts and other epithelial tumors. The compositions with two or more antigens that I had conceived and planned to use included compositions containing mumps and candida antigens, as well as compositions containing candida and bacterial antigens.

5. After receiving the approval letter from Dr. Faas, I proceeded to conduct the studies in humans that it refers to, successfully treating Verruca vulgaris in humans with the antigenic compositions. After I accumulated some data on treatment of humans, the data and a description of the invention were submitted to a patent attorney for filing of a patent application. The parent patent application was filed on June 25, 1999.

6. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true. Furthermore, these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and with knowledge that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 11/8/14 By: Thomas D. Horn

Thomas Dag Horn

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[redacted]

TITLE: "Application of Mumps and Candida Intradermal Skin Tests in Patients With Verruca Vulgaris" (None)(5014)

PRINCIPAL INVESTIGATOR: Thomas D. Horn, M.D.
Slot: 576

UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES
ASSURANCE #M-1451, IDENTIFICATION #01.

This application includes activities involving human subjects. Our institutional committee reviewed and approved it on [redacted] contingent on some corrections. These corrections were received and you may consider this your official approval letter in accordance with our assurance approved by the Public Health Service. This approval covers the protocol originally submitted and the revised consent form dated [redacted].

A study status report (continuing review) will be due in one year.

Please keep the committee advised of any changes, adverse reactions/deaths or termination of the study.

Fred H. Faas, M.D.
Chairman
Human Research Advisory Committee

FHF/ap

P.S. Also received with the above corrections was the addendum with the patient profile and data collection form (received [redacted]). I have reviewed this information and approving it by expedited review.